

24th September 2004

Newcastle Upon Tyne
NE2 2DP

Tel

RE EXPOSURE TO v CJD

Dear Dr,

Thank-you for your letter of 20th September 2004. My husband has asked me to write to you to confirm that he wishes to be informed in writing of all exposures he has had through plasma treatment to v CJD. He also wishes you to send him the specific batch numbers of any implicated treatment for his home records. We already have some batch numbers detailing earlier v CJD exposure, but if you could send details of all known implicated batches that would be helpful. If you could send us the information first, we will then decide whether there is any benefit to having an appointment at the hospital. We feel this way in view of the fact that my husband is still being denied the safer recombinant treatment, and the Primary Care Trust seem be adamant in it's decision not to treat him safely with regard to his haemophilia.

We would like to know whether my husband has surpassed the "at risk" threshold for public health purposes, as identified in the v CJD blood risk assessment carried out by Det Norske Veritas Consulting. We would also like information relating to the level of risk of any implicated batch numbers he has received, and the extent of his individual exposure. In other words, please don't hold back on any information relating to his exposure to v CJD.

We would like to point out some concerns and contradictory information which we have already read. In the information not sent to patients, we note that those patients exposed to v CJD will no longer be able to donate sperm, as a precautionary measure "for public health purposes". Given this directive, we feel it is important that patients exposed to v CJD are given specific advice on safe sexual practices, or perhaps the wives and partners of those exposed to v CJD are not included in the "for public health purposes" advice. Surely, if there is an "at-risk" element to the general public this must also apply to the families of haemophiliacs. We would like information on what specific advice/information will be given to those patients exposed to v CJD who are trying to conceive.

We raise these concerns because of past difficulties with HIV/hepatitis C, when for some time haemophiliacs were not given advice on safe sex because at that time there was no evidence of sexual transmission, and some haemophiliacs infected their wives and partners. No current evidence of sexual or mother to child transmission of v CJD does not necessarily mean we can assume that a risk does not exist. Is it not sensible to state this to haemophiliacs, and discuss the issue of erring on the side of caution, until more research has been carried out with regard to v CJD, so that patients can make an informed decision with regard to sexual practice.

We would like to inform you that in a recent phone call to Ermias Belay, at the CDC, Atlanta, who was most helpful, he agreed with us that U.S. plasma cannot be guaranteed to be v CJD free, particularly as for years UK donors were allowed to sell their blood in the States. There is also a need to keep an open mind over sexual transmission.

My friend's son from the UK who recently spent time in America as a student wrote to us testifying to his experience of selling blood in the U.S. on several occasions to help finance himself, through college. He informed us that he smoked

dope on the way to donate and was economical with the truth when answering questions in order not to be excluded, as he needed the money! This is one of the reasons why we feel so strongly about the blood for money trade, it compromises safety. We have other examples of Europeans from countries with cases of BSE/v CJD being accepted as plasma donors in the U.S.

This rather makes a mockery of our government importing U.S. plasma on the assumption that it is v CJD free. It is better that everyone is open about this issue. We are copying this letter to the Primary Care Trust so that they are fully informed that they are continuing to prescribe human plasma products derived from U.S. plasma to their haemophilia patients in the full knowledge that it cannot be guaranteed to be v CJD free, even though a safer treatment, recombinant, can be used as an alternative to human plasma.

We would like to state that we do not agree with the fact that no action should be taken regarding v CJD in relation to NON-UK plasma products. Given that European donors have for years donated plasma in the U.S. It makes sense to take the same action with patients treated with U.S. products as for those who have had UK products. Hopefully I will have the opportunity to raise this issue at a vCJD conference this Saturday. I have already spoken to the vCJD Surveillance Unit at Edinburgh, with regard to our concerns over U.S. plasma and I note that in a recent interview with Professor Ironside (enclosed), he raises the issue that as there is no test for v CJD we have no idea how many individuals in the U.S. have been exposed to BSE, and may be incubating the disease (v CJD) at present, and the need for surveillance.

We also note that there are two schools of thought with regard to “dilution” of v CJD in pooled plasma, one is that inactivation methods and pooling reduces the risk of infectivity, so the risk is low, the other is that v CJD may cause some of the plasma pool to be considered infective and therefore the risk level may be higher.

My husband and I are glad we went with our own moral code with regard to telling our GP and other hospital departments of his exposure to v CJD when we were first notified in writing in 2001. We went against the advice of the Haemophilia Centre not to tell our GP and other hospital departments because we thought this was unethical advice and we did not wish to put other patients or staff at risk. The hospital appears to have done a u-turn on its “don’t tell” policy now that recent guidelines have been issued from government to inform relevant others that a patient has been exposed to v CJD.

We were horrified in 2000 when we received leaked letters with regard to our own plasma company BPL (1997), and the Department Of Health Executive in Leeds (1998), and their advice not to tell haemophiliacs of their exposure to v CJD. We have no regrets about going to the press on this issue in October 2000 as documented in the “Guardian” and other newspapers. We are glad we spoke out in 2000, as stated in our interview on the PM programme on BBC Radio 4 this week. We note that the RVI hospital withheld information on my husband’s exposure to v CJD as noted in his medical records (1987), until 2001. We feel that this decision may have put other patients at risk. We wish to be informed in writing if other patients have been put at risk following this decision, and need to be notified, for example, with regard to the use of surgical instruments following any procedure performed on my husband.

Can you guarantee that haemophiliacs exposed to v CJD will not be discriminated against with regard to medical treatment? We are of course aware that many haemophiliacs may require liver transplants when their hepatitis C worsens. Can you guarantee that haemophiliacs will not be excluded from transplants because of

exposure to v CJD? What are the guidelines for dealing with potential infectivity to other patients following a procedure on a patient exposed to v CJD? Will hospitals be disposing of all instruments used on a person exposed to vCJD or will they be re-using these instruments. If re-use of surgical instruments is recommended, what will be the procedure for cleaning instruments, and can the Department of Health guarantee that there will be no infection risk to others? If not will they be open about this. I note the following in the information leaflet devised by the CJD Incidents

Panel:-

“Any risk of transmitting v CJD on such surgical instruments (that have come into contact with those “at-risk” of v CJD) will decrease each time they are used and decontaminated. After going through approximately ten cycles of use and standard decontamination, the instruments are unlikely to pose a significant risk of infection to other patients”.

Is cost a major issue in relation to policy over surgical instruments? We would imagine the cost of destroying instruments for example in a liver transplant would be very high.

When will carers of haemophiliacs be given written guidelines on how to deal with a blood spillage in those exposed to v CJD. Personally we don't want another incident where men in full bio-hazard suits have to remove blood-soiled carpets/furniture if my husband has a bleed at home. (As you know we photographed this incidence as evidence of difficulties we are experiencing). That particular incident was very upsetting, and there have been other incidents since then, when workmen putting in a disabled shower did not want to work in our property because my husband had been exposed to v CJD. There are no guidelines for those in the community, although there are guidelines in relation to v CJD in hospital. We fully understand that people are concerned for their own safety, and that is why there must be guidelines for those in the community, particularly with regard to blood spillage, as there are for HIV/hepatitis C.

Only a couple of weeks ago a chiropodist came to our home to treat my husband's feet and had not been informed that he had been exposed to vCJD, naturally she was not happy when we told her, as she had not been given this information from her colleagues. There was a safety issue for her. She was not able to treat my husband's feet as he needed a referral to a colleague at the hospital designated to deal with those patients that had been exposed to v CJD. If we had said nothing, the chiropodist would have treated my husband, and may then have used her instruments after normal sterilisation on another patient possibly putting them at risk.

With regard to the information we requested concerning old treatment batch numbers identified as “suspect” for hepatitis C. We do of course appreciate that you weren't working at the Haemophilia Centre at the time of the government funded study (1979-82) into haemophiliacs and hepatitis infection. This information would have been very useful to our American lawyers as it included information on American plasma treatment batch numbers considered higher risk for hepatitis than UK products. We do believe that this information will probably still exist and hope that we can achieve our aim of a full and open public inquiry into the blood contamination issue to access such information.

For several months now I have been assisting a campaign colleague with an historical overview and information pertaining to the mass contamination of haemophiliacs with blood borne viruses, for her speech at the Lib/ Dem Party Political Conference this week. I am glad to say that the motion for a public inquiry was very well supported with an overwhelming “yes” vote for a public inquiry. Charles

Kennedy spoke of the shocking way haemophiliacs had been treated over the years. Hopefully we will eventually force the government to be open on this issue and release many documents into the public domain through a full and open public inquiry.

We look forward to your reply. Thank-you for your assistance.

Yours sincerely

Mr and Mrs.....